UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE SUBOXONE (BUPRENORPHINE/NALOXONE) PRODUCTS LIABILITY LITIGATION	)	**Case No. 1:24-md-03092**
	)	**MDL No. 3092**
This Document Relates to All Cases	)	**Judge J. Philip Calabrese**

PLC'S NOTICE OF VIDEOTAPED FED. R. CIV. P. 30(B)(6) DEPOSITION OF THE CORPORATE REPRESENTATIVES FOR THE INDIVIOR DEFENDANTS (*CONCERNING 2022 SUBOXONE FILM LABEL CHANGE*)

PLEASE TAKE NOTICE that pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs, by and through the Plaintiffs' Leadership Committee, will take the deposition upon oral examination of the Indivior Defendants with respect to the topics set forth below. The deposition will take place on a date and at a location to be agreed by the parties before a notary public or other person authorized by law to administer oaths and take depositions, or at a mutually available time negotiated by the parties. The deposition will be recorded stenographically and by video recording. Plaintiffs reserve the right to use at the trial of this action the videotape recording of the deposition of the deponent pursuant to Fed. R. Civ. P. 32(a).

Plaintiffs reserve the right to seek relief from the Court in the event Defendants do not properly prepare the designated person(s) to testify on behalf of Defendants with respect to each of the identified topics.

Defendants are hereby requested and required under the federal rules to designate and produce at the deposition one or more officers, directors, managing agents, or other persons who consent to testify on their behalf on the following matters and documents:

DEFINITION

The term "2022 Label Change" means all June 2022 changes to the Suboxone Film prescribing information and patient Medication Guide concerning dental problems and dental care during Suboxone Film use.

SCHEDULE A: DEPOSITION SUBJECT MATTERS

1. The **substance** of the 2022 Suboxone Film label change, including the rationale for each of the changes made and the internal timeline of events leading up to the approval of changes by the FDA. To the extent any label changes are being considered at the present, this notice also covers the substance and rationale for those changes.

2. All formal **regulatory submissions and FDA communications** concerning the 2022 Suboxone Film label change. This includes any communications you and/or someone acting on your behalf had with FDA from the time FDA identified the dental safety signal in 2017 following publication of De Campaigno EP, et al. *Drug-Induced Dental Caries, Lessons from a Disproportionality Analysis in Vigibase: Because of Biphosphonates, Atropinic, Immunosuppressant and Hyperglycaemic Drugs*, Clinical Therapeutics (Aug. 2017), which concluded that buprenorphine/naloxone had "high

proportionality" for dental caries, through the January 12, 2022 FDA Drug Safety Communication, until the time of the formal label change in June 2022.

3. The sources of all **information considered by you** and/or relied upon in making the 2022 Suboxone Film label change. This includes, but is not limited to, any analyses, reports, clinical data, post-market surveillance, adverse-event reports, customer/physician feedback, marketing and/or sales considerations, and/or studies influencing your position on the label change.

4. Any **third-party involvement** in the 2022 Suboxone Film label change. This includes external consultants, vendors, advisory boards, lobbyists, physician organizations, and industry groups.

5. The identity of all **key decision makers**, including their respective department and/or functions, actively involved in the 2022 Suboxone Film label change and the details of each of their involvement.

6. The **training on and process of dissemination of the details** concerning the 2022 Suboxone Film label change **to your sales representatives and marketing** individuals.

7. The **content of and methods** by which details of the 2022 Suboxone Film label change were disseminated **to healthcare providers and the public**.

8. Any **post-label-change monitoring and/or analysis** conducted by you or on your behalf pertaining to the 2022 Suboxone Film label change. This includes, but is not limited to, any studies and/or reviews assessing the impact of the new label change language.

9. **Corporate policies and procedures on label changes** in effect at the time of the FDA's identification of the dental safety signal in 2017 through the 2022 Suboxone Film label change. If policies and procedures were changed throughout the label-change process, then this subject matter includes all versions in effect during the process.

10. To the extent not covered by any prior request, any **board and/or executive involvement** in decision making concerning the 2022 Suboxone Film label change.

11. To the extent you and/or anyone acting on your behalf interacted with any signatory to the January 24, 2022 "Call for the FDA to Retract its Safety Communication Regarding Buprenorphine" about the communication, the details of such interactions and the person(s) involved in the interactions.

12. To the extent any witness comes to the deposition with previously unproduced documents, the witness should be prepared to discuss the contents of those documents.

13. To the extent any witness has reviewed any documents to prepare for the deposition, the witness should be prepared to discuss the contents of those documents.

SCHEDULE B: DOCUMENTS TO BE PRODUCED

1. All documents which the deponent(s) has utilized or may need to refresh his or her recollection as to any of the subject matters referenced in **Schedule A**.

2. All documents the deponent(s) consults or relies upon in preparation for the deposition.

3. All documents the deponent(s) creates (or are created on his/her behalf) to address any of the subject matters referenced in **Schedule A**.

4. The most current CV and/or resume for each of the person(s) being deposed pursuant to this notice.

5. To the extent not previously produced in this litigation, your entire regulatory file, including formal FDA communications concerning the FDA's its identification of the dental safety signal in 2017, through the January 12, 2022 FDA Drug Safety Communication, and through the 2022 Suboxone Film label change.

6. All policies and procedures applicable to each step in the label-change process in effect at the time from 2017 through the 2022 Suboxone Film label change.

7. All official approved and published written communications to your sales force and marketing personnel, healthcare providers, and the public about the 2022 Suboxone Film label changes.

8. Organizational charts for any department, unit, or function tasked with any step in the 2022 Suboxone Film label change process, including organizational charts for each of the key decision makers identified pursuant to Subject Matter Number 5.

9. Any written agreement between you or someone acting on your behalf and any third party involved in the 2022 Suboxone Film label change, if applicable.

10. All internal meeting minutes, including those conducted between you and any third parties, including FDA, concerning the FDA's identification of the dental safety signal in 2017, the January 12, 2022 FDA Drug Safety Communication, and/or the 2022 Suboxone Film label change.

Dated: April 1, 2025

Respectfully submitted,

/s/ *Ashlie Case Sletvold*
Ashlie Case Sletvold
PEIFFER WOLF CARR KANE CONWAY & WISE, LLP
6370 SOM Center Road, Suite 108
Cleveland, Ohio 44139
(216) 589-9280
asletvold@peifferwolf.com

/s/ *Erin Copeland*
Erin Copeland
FIBICH, LEEBRON, COPELAND & BRIGGS
1150 Bissonnet Street
Houston, Texas 77005
(713) 424-4682
ecopeland@fibichlaw.com

/s/ *Timothy J. Becker*
Timothy J. Becker
JOHNSON // BECKER, PLLC
444 Cedar Street, Suite 1800
St. Paul, Minnesota 55101
(612) 436-1800
tbecker@johnsonbecker.com

/s/ *Trent B. Miracle*
Trent B. Miracle
FLINT COOPER LLC
222 East Park Street, #500
Edwardsville, Illinois 62025
(618) 288-4777
tmiracle@flintcooper.com

/s/ *Alyson Steele Beridon*
Alyson Steele Beridon
HERZFELD, SUETHOLZ, GASTEL,
LENISKI, & WALL, PLLC
600 Vine Street, Suite 2720
Cincinnati, Ohio 45202
(513) 381-2224
alyson@hsglawgroup.com
Plaintiffs' Co-Lead & Liaison Counsel

CERTIFICATE OF SERVICE

I hereby certify that on April 1, 2025, PLC's Notice of Videotaped Fed. R. Civ. P. 30(b)(6) Deposition of the Corporate Representatives for the Indivior Defendants (Concerning 2022 Suboxone Film Label Change) was served electronically on Defendants via their lead and liaison counsel.

Dated: April 1, 2025

/s/ *Ashlie Case Sletvold*
Ashlie Case Sletvold
PEIFFER WOLF CARR KANE
CONWAY & WISE, LLP
6370 SOM Center Road, Suite 108
Cleveland, Ohio 44139
(216) 589-9280
asletvold@peifferwolf.com

/s/ *Erin Copeland*
Erin Copeland
FIBICH, LEEBRON, COPELAND
& BRIGGS
1150 Bissonnet Street
Houston, Texas 77005
(713) 424-4682
ecopeland@fibichlaw.com

/s/ *Timothy J. Becker*
Timothy J. Becker
JOHNSON // BECKER, PLLC
444 Cedar Street, Suite 1800
St. Paul, Minnesota 55101
(612) 436-1800
tbecker@johnsonbecker.com

/s/ *Trent B. Miracle*
Trent B. Miracle
FLINT COOPER LLC
222 East Park Street, #500
Edwardsville, Illinois 62025
(618) 288-4777
tmiracle@flintcooper.com

/s/ *Alyson Steele Beridon*
Alyson Steele Beridon
HERZFELD, SUETHOLZ, GASTEL,
LENISKI, & WALL, PLLC
600 Vine Street, Suite 2720
Cincinnati, Ohio 45202
(513) 381-2224
alyson@hsglawgroup.com
Plaintiffs' Co-Lead & Liaison Counsel